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EXAMINER

HAWTHORNE, OPHELIA ALTHEA

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3772

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,372	Applicant(s) NELISSEN, JOZEF FRANS	
	Examiner OPHELIA HAWTHORNE	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13 - 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 - 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to amendments/arguments filed on 01/16/2009. Currently, claims 13 – 25 are pending in the instant application.

Response to Arguments

Applicant's arguments filed 01/16/09 have been fully considered but they are not persuasive. Applicant argues and asserts that neither Halstrom, nor Toone, either singly or in combination with each other, teach or suggested "the adjustable connection means comprise a horizontal screw for forward/backward adjustment of the one shaped part relative to the other" as recited in claim 13. Applicant further argues that a review of Toone indicates that Toone does not remedy the deficiencies of Halstrom. Applicant draws the Examiner's attention to FIGS. 9A and 9B of Toone which disclose a dental appliance with a threaded adjustment rod 50 (the Examiner's asserted "horizontal adjusting screw") which is received in threaded bore 52 to simultaneously adjust both the inferior and anterior position of the mandible portion of the dental appliance, as described in column 10, lines 30-66. In column 10, lines 47-51, Toone explains the importance of this simultaneous adjustment (i.e., the importance of causing adjustment rod 50 to simultaneously adjust the mandible portion forward/backward and upward/downward). Examiner respectfully disagrees with Applicant arguments indicating the importance of simultaneous adjustment, i.e. the importance of causing adjustment rod 50 to simultaneously adjust the mandible portion forward/backward and

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upward/downward. Toone teaches simultaneously adjusting the upper and lower mandibles, however, it's not as Applicant asserts, but rather simultaneously moving the anterior and inferior position of the appliance after fitting to the patient's dentition ([Col. 10], lines 30 - 34). In response to the applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of the primary (Halstrom) and secondary (Toone) references. In re Nomiya, 184 USPQ 607 (CCPA 1975). Halstrom substantially discloses an intra-oral appliance (20, Fig. 1) for treating sleep apnea comprising an adjustable connection means (40) for simultaneous forward/backward (via apertures 68, Fig. 7) and upward/downward adjustment (via stylus 46) since Halstrom teaches one appliance that simultaneously adjust the appliance forward/backward and upward/downward, it would have been obvious to one skill in the art to modify the oral appliance of Halstrom to have an horizontal screw for horizontal adjustment as taught by Toone for fine tune adjustment of the appliance. Furthermore, Halstrom discloses more than one connecting assembly (40) could be provided and the connecting assembly or assemblies could be mounted in a posterior rather than an anterior region of the dental appliance ([Col. 8], lines 52 - 56).

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "flange 17 and

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element 3" as describe in the specification must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in

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upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT WITH RESPECT TO FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claim 1 recites the limitation in lines 8 – 10 " the

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adjustable connecting means are fixedly connected to the other shaped part on one side and to the slide element on the other”, however, the original filed disclosure does not provide evidence that Applicant possessed “the adjustable connecting means are fixedly connected to the other shaped part on one side and to the slide element on the other” at the time the application was filed.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 19, 22 – 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 1, lines 10 – 12 recite the claim limitation “connected by means of a connecting piece” renders the claim vague and indefinite and is unclear to the Examiner. Is this a second connecting piece? Claim 19 recite the claim limitation “substantially in the middle” is unclear to the Examiner. In the middle of what? Claim 22 recite the claim limitation “of the one shaped part relative to the other co-acts on one outer end” which renders the claim vague and indefinite. What other shaped part is Applicant referring to? Claims 23 - 24 recite the claim limitation “the connecting piece” is unclear to the Examiner. Is this second connecting piece? Claim 25 recite the claim limitation “the adjustable connection means for the upwardly/downwardly adjustment” is unclear to the Examiner. Is this to indicate a separate connection means for the upward/downward from another connection means for the forward/backward adjustment?

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 13 – 14, 17 & 21 – 25 rejected under 35 U.S.C. 103(a) as being unpatentable over Halstrom (US 5,868,138) in view of Toone (US 4,901,737).

With respect to claim 13, Halstrom substantially discloses a device (20, Fig. 1) for treating breathing problems ([Col. 2] lines 44 – 46), comprising a shaped part (32) fitting onto the teeth of the lower jaw, a shaped part (28) fitting onto the teeth of the upper jaw, and at least one adjustable connecting means (40) between the upper (28) and lower (32) shaped part for forward/backward (apertures 68, Fig. 7) and upward/downward adjustment (stylus 46, Fig. 7) & ([Col. 6], lines 17 – 19) of the upper shaped part (28) relative to the lower shaped part (28), one of the shaped parts (32) is provided at the

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front with a slide mechanism (48) including a slide element (48) which is slidable laterally to a limited extent along a guide element (50), the adjustable connecting means (40) are fixedly connected to the other shaped part (32) on one side and to the slide element on the other (as shown in Fig. 7).

Halstrom substantially described the invention as claimed, except for the adjustable connection means comprising a horizontal adjusting screw for forward/backward adjustment of the one shaped part relative to the other, the screw being connected by means of a connecting piece with the adjustable connection means for the upward/downward adjustment. In addition, Halstrom discloses many alterations and modification are possible in the practice of his invention without departing from the spirit and scope thereof and more than one connecting assembly could be provided. Furthermore, Halstrom discloses the connecting assemble or assemblies could be mounted in a posterior rather than an anterior region of the dental appliance ([Col. 8], lines 49 – 56).

However, Toone teaches an apparatus for improving airway patency for reducing snoring and/or obstructive sleep apnea due to intermittent closures or partial obstructions in the oropharynx ([Col. 1], lines 11 – 14). The device (9a) comprising an horizontal screw or a threaded adjustment rod (50) & ([Col. 10], lines 65 – 66) for forward/backward adjustment of one of the shaped part (14) relative to the other, the screw or threaded adjustment rod (50) being connected by means of a connecting piece in the form of a threaded bore (52) for the upward/downward adjustment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was

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made to modify the connecting means of Halstrom to have a horizontal screw for forward/backward adjustment of the one shaped part relative to the other, the screw being connected by means of a connecting piece with the adjustable connection means for the upward/downward adjustment as taught by Toone in order to fine tune the dental appliance.

With respect to claim 14, Halstrom discloses the dimensions of the guide element (50) and the slide element (48) is closely-sized transversely of the guiding direction (as shown in Fig. 7).

With respect to claim 17, Halstrom discloses the slide element (48) can be snapped onto the guide element (50) via the cavity (54).

With respect to claim 18, Halstrom discloses the adjustable connecting means (40) comprising a substantially vertical adjusting screw (stylus 46) with double screw thread for upward/downward adjustment ([Col. 6], lines 17 – 19) of the upper shaped part (28) relative to the lower shaped part (32), which adjusting screw co-acts on one outer end with a first threaded bore (52) connected via a connecting piece to the slide element (48) and which co-acts on its other outer end with a second threaded bore (68) provided on the front side of the other shaped part (28), wherein a rotation of the adjusting screw (46) changes the distance between the lower and upper threaded bores ([Col. 7], lines 29 – 32).

With respect to claim 21, Halstrom discloses the adjustable connecting means (40) comprising a substantially vertical adjusting screw (46) and threaded bore (68) co-

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acting therewith for the upward/downward adjustment ([Col. 6], lines 17 – 19) of the upper shaped part (28) relative to the lower shaped part (32).

With respect to claim 22, Halstrom substantially described the invention as claimed, see rejection to claim 13 above; except the horizontal adjusting screw for forward/backward adjustment of the one shaped part relative to the other co-acts on one outer end with a threaded passage. In addition, Halstrom discloses many alterations and modification are possible in the practice of his invention without departing from the spirit and scope thereof and more than one connecting assembly could be provided. Furthermore, Halstrom discloses the connecting assemble or assemblies could be mounted in a posterior rather than an anterior region of the dental appliance ([Col. 8], lines 49 – 56).

However, Toone teaches an apparatus for improving airway patency for reducing snoring and/or obstructive sleep apnea due to intermittent closures or partial obstructions in the oropharynx ([Col. 1], lines 11 – 14). The device (9a) comprising an horizontal screw or a threaded adjustment rod (50) & ([Col. 10], lines 65 – 66) capable of forward/backward adjustment of one of the shaped part (14) relative to the other co-acts on one outer end with a threaded passage or a threaded bore (52). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the connecting means of Halstrom to have a horizontal screw for forward/backward adjustment of the one shaped part relative to the other co-acts on one outer end with a threaded passage as taught by Toone in order to fine tune the dental appliance.

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With respect to claim 23, Halstrom substantially described the invention as claimed, see rejection to claim 22; except for the threaded passage is provided in the slide element and the horizontal adjusting screw is provided on its other outer end with a screw head, the connecting piece being provided with a horizontally oriented hole through which the horizontal adjusting screw extends. In addition, Halstrom discloses many alterations and modification are possible in the practice of his invention without departing from the spirit and scope thereof ([Col. 8], lines 50 – 52).

However, Toone teaches an apparatus for improving airway patency for reducing snoring and/or obstructive sleep apnea due to intermittent closures or partial obstructions in the oropharynx ([Col. 1], lines 11 – 14). The device (9a) comprising a threaded passage (52) is provided in the slide element (53) and the horizontal screw (50) is provided on its outer end with a screw head (every screw has a head portion), the connecting piece being provided with a horizontal oriented hole (52) through which the horizontal adjusting screw extends. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the connecting means of Halstrom to have the threaded passage is provided in the slide element and the horizontal adjusting screw is provided on its other outer end with a screw head, the connecting piece being provided with a horizontally oriented hole through which the horizontal adjusting screw extends as taught by Toone since doing so would provide a means for reducing sleep apnea due to intermittent closures or partial obstruction in the oropharynx.

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With respect to claim 24, Halstrom substantially described the invention as claimed, see rejection to claim 22; except the threaded passage is provided in the connecting piece, and the slide element is provided with a horizontally oriented hole through which the horizontal adjusting screw extends. In addition, Halstrom discloses many alterations and modification are possible in the practice of his invention without departing from the spirit and scope thereof ([Col. 8], lines 50 – 52).

However, Toone teaches an apparatus for improving airway patency for reducing snoring and/or obstructive sleep apnea due to intermittent closures or partial obstructions in the oropharynx ([Col. 1], lines 11 – 14). The device (9a) comprising a threaded passage (52) is provided in the connecting piece (Fig. 9a) and the slide element (54) is provided with a horizontally oriented hole through which the horizontal adjusting screw (50) extends. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the connecting assembly of Halstrom to have threaded passage is provided in the connecting piece, and the slide element is provided with a horizontally oriented hole through which the horizontal adjusting screw extends taught by Toone since doing so would provide a means for reducing sleep apnea due to intermittent closures or partial obstruction in the oropharynx.

With respect to claim 25, Halstrom discloses the adjustable connection means (40) for the upward/downward adjustment are partially built in a shaped part (as shown in Fig. 7).

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8. Claims 15 – 16 & 19 - 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halstrom (US 5,868,138) in view of Toone (US 4,901,737 and further in view of Lowe (US 5,409,017).

With respect to claim 15, Halstrom and Toone substantially described the invention as claimed, see rejection to claim 13 above; except for the guide element is a rod mounted between two points of the one shaped part, and the slide element is a hollow tube slidable around this rod. In addition, Halstrom discloses many alterations and modification are possible in the practice of his invention without departing from the spirit and scope thereof ([Col. 8], lines 50 – 52).

However, Lowe teaches a mandible repositioning appliance (Fig. 2) for treatment of snoring and sleep apnea ([Col. 1], lines 44 - 46). The device having a guide element which is a rod (54, 56, Fig. 3) mounted between two points of one of the shaped part, and the slide element is a hollow tube (58, 60) slidable around the rod ([Col. 3], lines 30 – 36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the guide and slide elements of Halstrom and Toone wherein the guide element is a rod and the slide element is a hollow tube taught by Lowe since doing so would serve to maintain the axial alignment of the upper and lower shaped part and prevent relative rotation of the anterior and posterior sections.

With respect to claim 16, Halstrom and Toone substantially described the invention as claimed, see rejection to claim 13 above; except the length of the hollow tube is chosen as a function of the desired maximum lateral displacement. In addition,

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Halstrom discloses many alterations and modification are possible in the practice of his invention without departing from the spirit and scope thereof ([Col. 8], lines 50 – 52).

However, Lowe teaches a mandible repositioning appliance (Fig. 2) for treatment of snoring and sleep apnea ([Col. 1], lines 44 - 46). The device comprising hollow tubes or parallel guide passage (58, 60) capable of functioning at the desired maximum lateral displacement. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Halstrom and Toone comprising a slide element wherein the length of the hollow tube is chosen as a function of the desired maximum lateral displacement taught by Lowe in order to maintain the axial alignment of the upper and lower shaped part.

With respect to claim 19, Halstrom and Toone substantially described the invention as claimed, see rejection to claim 18 above; except for the adjusting screw is provided substantially in the middle with an encircling flange with radially directed openings in which a rod fits for the purpose of turning the adjusting screw through rotation of the rod. In addition, Halstrom discloses many alterations and modification are possible in the practice of his invention without departing from the spirit and scope thereof ([Col. 8], lines 50 – 52).

However, Lowe teaches a mandible repositioning appliance (Fig. 2) for treatment of snoring and sleep apnea ([Col. 1], lines 44 - 46). The device comprising an adjusting screw or threaded nut (68) provided substantially in the middle (as shown in Fig. 3) encircling a flange (76) with radially directed openings (78) in which a rod (82) & ([Col. 3], lines 60 – 61) fits for the purpose of turning the adjusting a screw through rotation of

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the rod. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the adjusting screw of Halstrom and Toone to have a flange with directed openings in which a rod fits taught by Lowe in order to rotate the adjusting member and thus adjust the axial relative positions of both the upper and lower shaped parts.

With respect to claim 20, Halstrom and Toone substantially described the invention as claimed, see rejection to claim 18 above; except for the vertical adjusting screw is enclosed on both sides by telescopically acting tubes. In addition, Halstrom discloses many alterations and modification are possible in the practice of his invention without departing from the spirit and scope thereof ([Col. 8], lines 50 – 52).

However, Lowe teaches a mandible repositioning appliance (Fig. 2) for treatment of snoring and sleep apnea ([Col. 1], lines 44 - 46). The device comprising a vertical adjusting screw (70) enclosed on both sides by telescoping acting tube (74). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Halstrom and Toone to have telescoping acting tubes by which a vertical adjusting screw can be enclosed taught by Lowe in order to limit lateral movement of the upper and lower shaped part.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OPHELIA HAWTHORNE whose telephone number is

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(571)270-3860. The examiner can normally be reached on Monday - Friday, 7:30 AM - 5:00 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information With respect to the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ophelia Hawthorne/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772
5/8/09